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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/049,702

04/15/2002

Camilo Anthony Leo Selwyn Colaco

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09/07/2010

DRINKER BIDDLE & REATH  
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EXAMINER

GRASER, JENNIFER E

ART UNIT

PAPER NUMBER

1645

NOTIFICATION DATE

DELIVERY MODE

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ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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penelope.mongelluzzo@dbr.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/049,702	<b>Applicant(s)</b> COLACO, CAMILO ANTHONY LEO SELWYN	
	<b>Examiner</b> Jennifer E. Graser	<b>Art Unit</b> 1645	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 June 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 8-11 and 14-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8-11 and 14-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/7/10</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/7/10 has been entered.

### ***Claim Rejections - 35 USC § 112-Written Description and New Matter***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 8-11 and 14-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In 1999, the United States Patent and Trademark Office ("USPTO") published training materials regarding the examination of patent applications under the written description requirement of 35 U.S.C. § 112, first paragraph. (See [http://www.uspto.gov/web/offices/pac/writtende sc.pdf](http://www.uspto.gov/web/offices/pac/writtende%20sc.pdf)). Since that time, the case

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law and technology have developed in such a way as to necessitate a revision of the 1999 training materials. Consequently, this 2008 revision was created to supersede and replace the 1999 training materials. To the extent that any conflict exists between the 1999 training materials and the present materials, the present materials control. The claims have been evaluated with regard to written description based on the Written Description Guidelines and Training Materials published in 2008/

The instant claims are drawn to “composition capable of eliciting both a cytotoxic T-cell and an antibody based an immune response comprising an immunogenic determinant, wherein the immunogenic determinant comprises a mixture of complexes between a stress induced stress protein and an antigenic peptide fragment, wherein:

the complexes are obtained from a cell which has been infected with a bacterial, protozoal or parasitic intracellular pathogen, which infected cell has been subjected to stress from heat or tumor necrosis factor sufficient to stimulate the presence of stress proteins within the infected cell,

the stress proteins of the stress protein complexes are derived from the infected cell or~ and from the intracellular pathogen,

the antigenic peptide fragment of the stress protein complexes is derived from the intracellular pathogen, and

the immunogenic determinant comprises stress protein complexes which are not purified to homogeneity. “

To fulfill the written description requirements set forth under 35 USC § 112, first paragraph, the specification must describe at least a substantial number of the members of the claimed genus, or alternatively describe a representative member of the claimed genus, which shares a particularly defining feature common to at least a substantial number of the members of the claimed genus, which would enable the skilled artisan to immediately recognize and distinguish its members from others, so as to reasonably convey to the skilled artisan that Applicant has possession the claimed invention. Applicants have not described the genus of claimed complexes such that the

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specification might reasonably convey to the skilled artisan that Applicants had possession of the claimed invention at the time the application was filed.

The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the "written description" inquiry, whatever is now claimed. See *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Federal Circuit, 1991). Furthermore, the written description provision of 35 USC § 112 is severable from its enablement provision; and adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. The Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, paragraph 1, "'Written Description' Requirement (66 FR 1099-1111, January 5,2001) state, "[p]ossession may be shown in a variety of ways including description of an actual reduction to practice, or by showing the invention was 'ready for patenting' such as by disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention" (*Id.* at 1104). Moreover, because the claims encompass a genus of variant species, an adequate written description of the claimed invention must include sufficient description of at least

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a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics sufficient to show that Applicant was in possession of the claimed genus. However, factual evidence of an actual reduction to practice has not been disclosed by Applicant in the specification; nor has Applicant shown the invention was "ready for patenting" by disclosure of drawings or structural chemical formulas that show that the invention was complete; nor has Applicant described distinguishing identifying characteristics sufficient to show that Applicant were in possession of the claimed invention at the time the application was filed. The Guidelines further state, "[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus" (Id. at 1106); accordingly, it follows that an adequate written description of a genus cannot be achieved in the absence of a disclosure of at least one species within the genus. As evidenced by Greenspan et al (Nature Biotechnology 7: 936-937, 1999), defining epitopes is not as easy as it seems. Greenspan et al recommends defining an epitope by the structural characterization of the molecular interface between the antigen and the antibody is necessary to define an "epitope" (page 937, column 2). According to Greenspan et al, an epitope will include residues that make contacts with a ligand, here the antibody, but are energetically neutral, or even destabilizing to binding. Furthermore, an epitope will not include any residue not contacted by the antibody, even though substitution of such a residue might profoundly affect binding. Chothia et al (THE EMBO JOURNAL, 1986, 5/4:823-26) also teach that

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there is a limit to how much substitution can be tolerated before the original tertiary structure is lost. Therefore, absent a detailed and particular description of a representative number, or at least a substantial number of the members of the genus of complexes, the skilled artisan could not immediately recognize that Applicants were in possession of the claimed genus of peptides at the time of filing.

The scope of the claim includes numerous structural variants and the genus is highly variant because a significant number of structural differences between genus members is permitted. The specification does not describe any members of the claimed genus by complete structure. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus, and thus, that the applicant was not in possession of the claimed genus. The claimed subject matter is not supported by an adequate written description because a representative number of species has not been described.

There are no drawings or structural formulas disclosed of *any* of these immunogenic complexes. There is no teaching in the specification regarding which part of the structure can be varied and still produce a fragment which can elicit both a cytotoxic T-cell and an antibody based response.

Based on the lack of knowledge and predictability in the art, those of ordinary skill in the art would not conclude that the applicant was in possession of the claimed *genus* of complexes.

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Additionally, written support cannot be found for any stress proteins that are produced by an intracellular pathogen, e.g., as opposed to the cell it infects and causes the host cell to produce the stress protein. Members of stress proteins (SPs) of mammalian origin are described on page 2, lines 10-20. There is discussion of complexes between viral or tumor-associated antigenic peptide fragments and SPs produced by the mammalian cell (see paragraph bridging pages 2-3). This passage does not describe stress proteins derived from the virus or any intracellular pathogen or parasite. The originally presented claims and the paragraph on page 5, beginning at line 5 recite:

a method for producing a vaccine composition comprising an immunogenic determinant active component, characterised in that it comprises the steps of:

- a) subjecting cells infected with an intra-cellular bacterial, protozoan or parasitic pathogen to stress with heat or tumour necrosis factor; and
- b) extracting the endogenous stress-induced products, notably the SP/antigenic peptide fragment complexes, from the stressed cells [the eukaryotic cells]; and
- c) using the extracted products as the immunogenic determinant in the preparation of the vaccine composition.

This does not describe or provide any written support for stress proteins derived from the intracellular pathogen itself, e.g., it only describes the pathogen inducing the host cell to produce stress proteins of its own. Pages 5 and 6 specifically recite that GroEL, GroES, DnaK and DnaJ families of proteins are preferred from bacterial pathogens and related families in other extra-cellular pathogens. Pages 9 and 10 describe inducing cells which are infected by pathogens and intra-cellular pathogens to produce stress proteins, but do not recite that stress protein is produced by the pathogen itself. None of the examples provided describe or show the use of stress



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proteins produced by an intracellular-pathogen. Applicants must point to specific support for this by page and line number or remove the subject matter from the claims.

Factors to be considered in determining whether undue experimentation is required, are set forth in *In re Wands* 8 USPQ2d 1400. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims.

Applying the above test to the facts of record, it is determined that 1) no declaration under 37 C.F.R. 1.132 or other relevant evidence has been made of record establishing the amount of experimentation necessary, 2) insufficient direction or guidance is presented in the specification with respect specific fragments or complexes which induce both a cytotoxic and antibody based immune response; no specific structures are described. Additionally, none of the examples provided describe or show the use of stress proteins produced by an intracellular-pathogen, nor is there any written description for such stress proteins, 3) the relative skill of those in the art is commonly recognized as quite high (post-doctoral level). With regard to (4) the nature of the invention and (5) the state of the prior art, these have been discussed above. One of skill in the art would require guidance, in order to make or use the compositions as instantly claimed.

***Response to Applicants' arguments:***

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Applicants' arguments overcame the former Written Description rejection, but are moot with respect to the new Written Description set forth above.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 8-11 and 14-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Srivastava et al (WO 95/24923).

Srivastava et al disclose vaccines and compositions comprising stress protein-peptide complexes. They specifically teach heat shock proteins (HSP) may be used as the stress protein. Srivastava et al define 'stress protein' as a protein whose intracellular concentration increases when exposed to stressful stimuli, is capable of binding to other proteins or peptides, and is capable of releasing the bound proteins in the presence of ATP or low pH. See page 10, lines 9-13. Srivastava et al define stressful stimuli to "include, but [are] not limited to, heat shock, nutrient deprivation, metabolic disruption, oxygen radicals, and infection with intracellular pathogens". See page 10, lines 13-15. Srivastava et al teach that they have discovered that a stress protein-peptide complex when isolated from a eukaryotic cell infected with a preselected intracellular pathogen

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and then administered to a mammal can stimulate a cytotoxic T cell response directed against cells infected with the same pathogen. See page 19, lines 1-9. Srivastava et al teach that the stress proteins can accumulate to very high levels in stressed cells, but they occur low to moderate levels in cells that have not been stressed. They give the example of Hsp70 which is hardly detectable at normal temperatures but becomes one of the most actively synthesized proteins in the cell upon heat shock and Hsp90 and Hsp60 are abundant at normal temperatures in almost all mammalian cells, but are even further induced at by heat. See bottom of page 23. Srivastava et al teach that their immunogenic stress protein-peptide complexes may include any complex containing a stress protein and a peptide that is capable of inducing an immune response in a mammal. See page 23, lines 20-27. **The complexes can be prepared from cells infected with an intracellular pathogen as well as cells that have been transformed by an intracellular pathogen.** See page 24, lines 5-10. Pages 46-48 teach that adjuvants and/or pharmaceutically carriers may be used. Page 13, lines 1-15 teach that the complexes may be infected with bacterial, protozoal or parasitic intracellular organisms. Claim 15 specifically recites the 'stress' to be subjection to tumor necrosis factor. However, this is a product-by-process claim (as are all of the claims), "The patentability of a product does not depend upon its method of production. If the product in [a] product-by-process claim is the same as or obvious from a product of the prior art, [then] the claim is unpatentable even though the prior [art] product was made by a different process." In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). Once the examiner provides a rationale tending to show that the

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claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 218 USPQ 289, 292 (Fed. Cir. 1983). There does not appear to be a structural difference between the product claimed and the product taught by the prior art, e.g., the claimed compositions solely comprise an immunogenic determinant any complex comprising a stress protein and an antigenic peptide fragment. Srivastava et al teach that their immunogenic stress protein-peptide complexes may include any complex containing a stress protein and a peptide that is capable of inducing an immune response in a mammal. See page 23, lines 20-27. Srivastava et al specifically teach the complexes can be prepared from cells infected with an intracellular pathogen as well as cells that have been transformed by an intracellular pathogen. See page 24, lines 5-10.

6. Claims 8-11 and 14-16 remain rejected under 35 U.S.C. 102(e) as being anticipated by Srivastava et al (US 5,961,979).

Srivastava teaches a vaccine composition comprising an immunogenic determinant comprising one or complexes between a shock protein and an antigenic peptide from the heat stressing of a cell infected with a bacterial, protozoal or parasitic intra-cellular pathogen (see title, abstract and claims). Srivastava teaches that a vaccine containing a stress protein peptide complex when isolated from cells infected with an intracellular pathogen and then administered to a mammal can effectively stimulate immune response against the pathogen (see column 4, line 60-68 summary of the

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invention). Srivastava teaches bacteria and protozoa (see column 7, lines 1-15).

Srivastava teaches pharmaceutical carriers including aqueous composition and adjuvants (see column 23, lines 19-68). Srivastava teaches a method of producing the stress proteins including heat shock proteins and complex vaccine (see columns 5, 13 and 14). The prior art teaches the claimed invention. . Claim 15 specifically recites the 'stress' to be subjection to tumor necrosis factor. However, this is a product-by-process claim (as are all of the claims), "The patentability of a product does not depend upon its method of production. If the product in [a] product-by-process claim is the same as or obvious from a product of the prior art, [then] the claim is unpatentable even though the prior [art] product was made by a different process." In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 218 USPQ 289, 292 (Fed. Cir. 1983). There does not appear to be a structural difference between the product claimed and the product taught by the prior art, e.g., the claimed compositions solely comprise an immunogenic determinant any complex comprising a stress protein and an antigenic peptide fragment.

*Response to applicant's arguments:*

Applicants' arguments address both Srivastava patents so they will be addressed together. These arguments have been fully and carefully considered but are not

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deemed persuasive. Applicants argue that Strivastava describe stress peptide complexes purified to homogeneity. They argue that, accordingly, these complexes can comprise only a single stress protein species. They quote page 28, line 20, of WO 95/24923 "the Hsp-70-peptide complex can be purified to apparent homogeneity using this method". These arguments are not commensurate in scope with the claimed invention. The claims do not require the use of more than one stress peptide. In fact the claims recite the complex is between a stress induced protein [not plural] and an antigenic determinant. Strivastava state that the complex "can" be purified to homogeneity but do not require it.

Applicants also argue that their complexes are capable of eliciting both cell-mediated CTL responses as well as humoral antibody response as evidenced by the passage at page 14, lines 8-17, of the specification for support. This passage recites:

In order to determine the immunogenicity of the SP complexes, T cell proliferation assays may be used. Suitable assays include the mixed-lymphocyte reaction (MLR), assayed by tritiated thymidine uptake, and cytotoxicity assays to determine the release of <sup>51</sup>Cr from target cells, see 'Current Protocols in Immunology', Wiley Interscience, 1997. Alternatively, antibody production may be examined, using standard immunoassays or plaque-analysis assays, or assessed by intrauterine protection of a foetus, see ~Current Protocols in Immunology'.

Applicants argue that Strivastava merely teaches the induction of T-cell immune responses. This argument has been fully and carefully considered but is not deemed persuasive. Strivastava does teach that for immunizing against an intracellular pathogen it is a necessity to elicit a strong cytotoxic T-cell response. They teach that subunit vaccines were known to produce good humoral immune responses but failed to elicit strong T-cell immune response. Strivastava sought to find a composition which could effectively elicit a T-cell immune response. The HSPs in the complexes were well known in the prior art, as also taught by, Strivastava for elicit an antibody based

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immune response. The fact that Srivastava teaches that a strong T-cell immune response was raised does not negate or teach away from there also being an antibody immune response present. Since Srivastava teaches structurally analogous structures, they would inherently produce the same types of immune responses.

Additionally, the instant claims recite 'an immunogenic determinant comprising any induced stress protein and any antigenic peptide *obtained* from, a cell which has been infected with....". Srivastava et al teach an immunogenic determinant comprising any induced stress protein and any antigenic peptide. The claims are product-by-process claims. "The patentability of a product does not depend upon its method of production. If the product in [a] product-by-process claim is the same as or obvious from a product of the prior art, [then] the claim is unpatentable even though the prior [art] product was made by a different process." In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 218 USPQ 289, 292 (Fed. Cir. 1983). There does not appear to be a structural difference between the product claimed and the product taught by the prior art, e.g., the claimed compositions solely comprise an immunogenic determinant any complex comprising a stress protein and an antigenic peptide fragment. While a specific stressor may cause more stress protein and stress protein complexes to be induced, it does not appear to change the structure of the complex, nor does the claim require a specific level of complex. Srivastava et al do not solely teach

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constitutively expressed complexes. Srivastava discloses the claimed compositions produced by a stress process and isolated from natural sources, produced in situ. The bacterial heat shock protein (see Table 1 and definitions) is complexed together with an antigenic peptide fragment from a bacteria (see col. 7, line 7 "Chlamydia"), fungus, or protozoa, wherein the heat shock protein complex is isolated from natural sources (see col. 21, line 28). Accordingly, Srivastava et al anticipates the claimed compositions.

Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Remsen. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1645 Fax number is 571-273-8300 which is able to receive transmissions 24 hours/day, 7 days/week.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (571) 272-0858. The examiner can normally be reached on Monday-Thursday from 8:00 AM-6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached on (571) 272-0832.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0500.

/Jennifer E. Graser/  
Primary Examiner, Art Unit 1645

8/25/10